

WHAT IS CLAIMED IS:

1. A pharmaceutical composition comprising particulate valdecoxib in an amount of about 1 mg to about 100 mg per dose and one or more pharmaceutically acceptable excipients, wherein a single dose, upon oral administration to a
5 fasting subject, provides a time course of blood serum concentration of valdecoxib having at least one of
(a) a time to reach a threshold concentration for therapeutic effect not greater than about 0.5 h after administration;
(b) a time to reach maximum concentration (T_{max}) not greater than about 5 h
10 after administration; and
(c) a maximum concentration (C_{max}) not less than about 100 ng/ml.
2. The composition of Claim 1 wherein the threshold concentration for therapeutic effect is about 20 ng/ml.
3. The composition of Claim 2 wherein a single dose, upon oral administration to a
15 fasting subject, provides a time course of blood serum concentration of valdecoxib having each of
(a) a time to reach a concentration of 20 ng/ml not greater than about 0.5 h after administration;
(b) a time to reach maximum concentration (T_{max}) not greater than about 3 h
20 after administration; and
(c) a maximum concentration (C_{max}) not less than about 100 ng/ml.
4. The composition of Claim 1 wherein the valdecoxib is in an amount of about 5 mg to about 40 mg per dose.
5. The composition of Claim 1 that is a tablet wherein the excipients comprise one
25 or more diluents in an amount of about 5% to about 99%, one or more disintegrants in an amount of about 0.2% to about 30%, one or more binding agents in an amount of about 0.5% to about 25%, and one or more lubricants in an amount of about 0.1% to about 10%, by weight of the composition.
6. The composition of Claim 5 wherein the binding agent is pregelatinized starch.

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7. The composition of Claim 1 that is a tablet wherein the excipients comprise lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, pregelatinized starch and magnesium stearate.
 8. The composition of Claim 1 further comprising one or more opioid or analgesic drugs.
 - 5 9. The composition of Claim 1 wherein D₉₀ of the valdecoxib particles is less than about 75 µm.
 - 10 10. The composition of Claim 1 wherein the valdecoxib particles have a weight average particle size of about 1 to about 10 µm.
 11. A process for preparing a composition of Claim 5 comprising a step of wet granulating valdecoxib together with one or more diluents and a binding agent, a step of drying the resulting granules and a step of compressing the resulting dry granulate to form a tablet.
 12. The process of Claim 11 wherein, prior to the wet granulating step, valdecoxib is mixed under low shear with one or more diluents and a binding agent to form a premix for wet granulation; and wherein, between the drying step and the compressing step, the granules are blended with a disintegrant and a lubricant to form a blend for tableting.
 - 15 13. The process of Claim 12 wherein the binding agent is pregelatinized starch.
 14. The process of Claim 13 wherein the diluents comprise lactose monohydrate and microcrystalline cellulose, the disintegrant is croscarmellose sodium and the lubricant is magnesium stearate.
 - 20 15. The process of Claim 11 wherein, prior to the wet granulating step, valdecoxib is mixed under high shear with a primary diluent, a first portion of a secondary diluent, a binding agent and a first portion of a disintegrant, to form a premix for wet granulation; and wherein, between the drying step and the compressing step, the granules are blended with a second portion of the secondary diluent, a second portion of the disintegrant, and a lubricant, to form a blend for tableting.
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16. The process of Claim 15 wherein the binding agent is pregelatinized starch.
17. The process of Claim 16 wherein the diluents comprise lactose monohydrate and microcrystalline cellulose, the disintegrant is croscarmellose sodium and the lubricant is magnesium stearate.
- 5 18. A method of treating a medical condition or disorder in a subject where treatment with a cyclooxygenase-2 inhibitor is indicated, comprising orally administering to the subject a composition of Claim 1 once or twice a day.

DRAFT - SUBJECT TO CHANGE